Remarks/Arguments:

Introduction

Claims 1-32 are pending. Claims 1 and 11 have been amended.

Section 103 Rejections

Claims 1-32 are rejected under 35 U.S.C. § 103a) as allegedly being unpatentable over U.S. Patent No. 6,290,720 to Khosravi et al. ("Khosravi") in view of U.S. Patent No. 5,922,339 to Usala ("Usala"). Applicants traverse.

Khosravi is directed to a stent-graft. (Khosravi, column 1, line 64). The graft is a tubular graft of "polyester, polytetrafluorethaline [sic], dacron, teflon or polyurethane". (Khosravi, column 2, lines 42-43). The stent is attached to the graft by sutures, staples, wires, adhesive bonding, thermal bonding, chemical bonding or ultrasonic bonding. (Khosravi, column 2, lines 43-46).

Khosravi, however, fails to teach or suggest a graft made from or comprising poly-para-xylylene. Moreover, Khosravi fails to teach any physical properties of its tubular graft, such as wall thickness.

Usala teaches that certain polymer coatings, such as poly-para-xylylene, are useful against immune response for artificial organs and other transplants of both living and nonliving tissue. (Usala, column 2, lines 27-34). The coatings could be applied to stents, grafts, catheters or shunts. (Usala, column 5, lines 61-64). The coatings are generally very thin at 100 to 200 Angstroms (0.01 to 0.02 microns), but could be as thick as 2,000 Angstroms (0.2 microns).

(Usala, column 5, lines 34-35, lines 54-55). Usala further discloses membranes of poly-para-xylylene with a maximum thickness of about 7,500 Angstroms (0.75 microns).

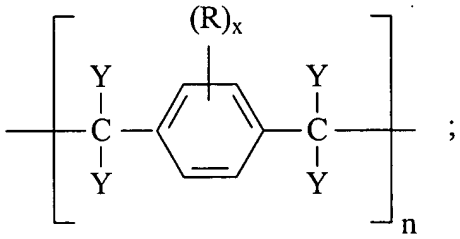
Thus, Usala is directed to very thin coatings or membranes of poly-para-xylylene having a thickness in the Angstrom range.

For the reasons discussed below, claims 1-32 are patentably distinct over Khosravi and Usala.

Patentability of Independent Claims 3, 8, 29 and 32:

In contrast to Khosravi and Usala, the present invention as presently defined in Claim 3 is directed to an implantable stent-graft device comprising (i) a seamless and self supporting tubular non-textile graft of biocompatible polymeric material having a wall thickness of about 10 microns to about 100 microns defining a luminal surface and an exterior surface; and (ii) a radially expandable stent securably disposed over portion of said exterior surface. (emphasis added).

In further contrast to Khosravi and Usala, the present invention as presently defined in Claim 8 is directed to a stent-graft endoprosthesis comprising (i) a seamless tubular non-textile graft of biocompatible polymeric material having a wall thickness of about 10 microns to about 250 microns defining a luminal surface and an exterior surface; and (ii) a radially expandable stent securably disposed over portion of said exterior surface; wherein said polymeric material comprises a poly-para-xylylene having a formula of



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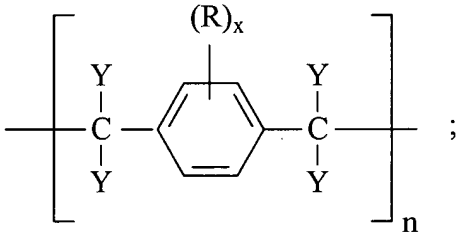
wherein n is from about 10 to about10,000, x is from 0 to 4, R, which can be the same or different, is alkyl, aryl, alkenyl, amino, cyano, carboxyl, alkoxy, hydroxylalkyl, carbalkoxy, hydroxyl, nitro, chlorine, bromine, iodine and fluorine, and Y, which can be the same or different, is hydrogen, chlorine, bromine, iodine and fluorine. (emphasis added).

In yet further contrast to Khosravi and Usala, the present invention as presently defined in Claim 29 is directed to an endoprosthesis comprising (i) a seamless tubular non-textile graft of biocompatible polymeric material having a wall thickness of about 10 microns to about 250 microns defining a luminal surface and an exterior surface; wherein said polymeric material is a poly-para-xylylene having a formula of



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wherein n is from about 10 to about10,000, x is from 0 to 4, R, which can be the same or different, is alkyl, aryl, alkenyl, amino, cyano, carboxyl, alkoxy, hydroxylalkyl, carbalkoxy, hydroxyl, nitro, chlorine, bromine, iodine and fluorine, and Y, which can be the same or different, is hydrogen, chlorine, bromine, iodine and fluorine. (emphasis added).

In still further contrast to Khosravi and Usala, the present invention as presently defined in Claim 32 is directed to an implantable graft device comprising (i) a seamless and self supporting tubular non-textile graft of biocompatible polymeric material having a wall thickness of about 10 microns to about 100 microns and having opposed open ends to define a fluid passageway therebetween. (emphasis added).

Khosravi and Usala fail to teach or suggest the present invention of claims 3, 8, 29 and 32. Except for a graft being made from polymeric material (but excluding poly-para-xylylene),

Khosravi fails to teach or suggest any additional physical properties of its graft, including wall thickness of its graft. Usala fails to teach or suggest a graft with a wall thickness from about 10 to about 100 microns or from about 10 to about 250 microns. Usala is directed to very thin coatings or membranes that are Angstrom-sized in thickness. Thus, the combination of Khosravi and Usala fail to teach or suggest the present invention as set forth in claims 3, 8, 29 and 32 because the combination fails to teach or suggest a self-supporting tubular graft having a wall thickness of about 10 microns to about 100 microns or poly-para-xylylene graft having a wall thickness from about 10 microns to about 250 microns.

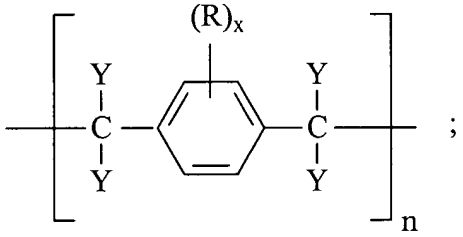
Further, Applicants respectfully disagree with the Examiner's that the "range of the wall thickness of the graft as claims is known in the art". (Office Action, page 3). As noted in paragraph [0049] of the Specification, prior art grafts have minimum wall thicknesses in the millimeter range (as contrasted to the micron-sized range), with the exception of expanded polytetrafluoroethylene grafts which may have a minimum wall thickness of about 200 microns. As described in paragraph [0049], however, such thin-walled expanded polytetrafluoroethylene grafts are not self-supporting.

Thus, despite the Examiner's assertion that the claimed wall thicknesses are allegedly known in the art, Applicants respectfully submit that the recitations of self-supporting and the wall thicknesses of claims 3 and 32 are not taught nor suggested by the prior art, including the prior art of record for the present application. Further, the recitation of a poly-para-xylylene graft with a wall thickness of about 10 to about 250 microns, as set forth in claims 8 and 29, is neither taught nor suggested in the prior art, including the prior art of record for the present application.

Therefore, reconsideration and withdrawal of the rejections of claims 3, 8, 29 and 32, and all claims dependent therefrom, under 35 U.S.C. § 103(a) are respectfully requested.

Patentability of Independent Claims 1, 11, 16 and 27:

In contrast to Khosravi and Usala, the present invention as presently defined in Claim 1 is directed to a stent-graft endoprosthesis comprising (i) a seamless tubular graft of biocompatible polymeric material having a wall thickness defining a luminal surface and an exterior surface; (ii) a radially expandable coated stent securably, circumferentially and axially disposed over said exterior surface, wherein said coated stent is coated with said biocompatible polymeric material; wherein said biocompatible polymeric material consists essentially of poly-para-xylylene having a formula of



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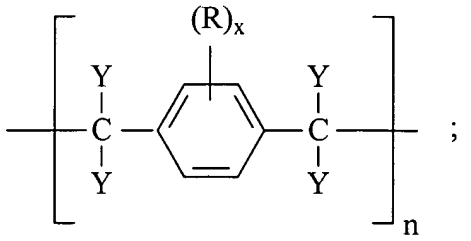
wherein n is from about 10 to about10,000, x is from 0 to 4, R, which can be the same or different, is alkyl, aryl, alkenyl, amino, cyano, carboxyl, alkoxy, hydroxylalkyl, carbalkoxy, hydroxyl, nitro, chlorine, bromine, iodine and fluorine, and Y, which can be the same or different, is hydrogen, chlorine, bromine, iodine and fluorine.

In further contrast to Khosravi and Usala, the present invention as presently defined in Claim 11 is directed to a stent-graft endoprosthesis comprising (i) a seamless tubular non-textile graft of biocompatible polymeric material having a wall thickness defining a luminal surface and an exterior surface; and (ii) a radially expandable stent securably disposed over a portion of said exterior surface; wherein said polymeric material consists essentially of a poly-para-xylylene having a formula of



wherein n is from about 10 to about10,000, x is from 0 to 4, R, which can be the same or different, is alkyl, aryl, alkenyl, amino, cyano, carboxyl, alkoxy, hydroxylalkyl, carbalkoxy, hydroxyl, nitro, chlorine, bromine, iodine and fluorine, and Y , which can be the same or different, is hydrogen, chlorine, bromine, iodine and fluorine.

In yet further contrast to Khosravi and Usala, the present invention as presently defined in Claim 16 is directed to a method for producing a stent-graft endoprosthesis comprising the steps of (i) providing a mandrel having a cylindrical outer surface; (ii) depositing a poly-para-xylylene polymer onto a portion of said outer surface of said mandrel to form a tubular polymeric graft having a wall thickness defining a luminal surface and an exterior surface of said graft; (iii) providing a radially expandable stent; and (iv) securing portions of said stent to portions of said outer surface of said graft to form said stent-graft endoprosthesis.

In still further contrast to Khosravi and Usala, the present invention as presently defined in Claim 27 is directed to a method for producing a stent-graft endoprosthesis comprising the steps of (i) providing a tubular graft of vacuum vapor deposited poly-para-xylylene polymer; (ii) providing a radially expandable stent; and (iii) securing portions of said stent to portions of said outer surface of said graft to form said stent-graft endoprosthesis.

Applicants respectfully submit that Khosravi and Usala fail to teach or suggest a tubular graft consisting essentially of poly-para-xylylene as set forth in independent claims 1 and 11. As described above, Khosravi fails to teach or suggest a graft consisting essentially of poly-para-xylylene. Usala merely teaches that a graft or a stent may be coated with a very thin,

Angstrom-sized coating of poly-para-xylylene. While Usala fails to disclose the material of construction of the underlying graft, the underlying graft cannot be poly-para-xylylene because the coating of Usala is applied to the underlying to change the property of the underlying graft, such as tissue or cell adherence of the underlying graft. (Usala, column 5, lines 54-64). Accordingly fails to teach or suggest a graft consisting essentially of poly-para-xylylene. Therefore, the combination of Khosravi and Usala fail to teach the present invention because neither teach nor suggest a polymeric graft consisting essentially of poly-para-xylylene. Thus, because of the deficiencies in the Khosravi and Usala references the only way to arrive at the present invention from such a combination of references is through hindsight reconstruction using Applicants' own Specification as a roadmap. Such hindsight reconstruction, however, is impermissible and fails to present a *prima facie* case of obviousness.

Thus, the stent-graft endoprostheses of claims 1 and 11 are patentably distinct over Khosravi and Usala. Further these references also fail to teach or suggest the methods for producing stent-graft endoprostheses according to claims 16 and 27 of the present application.

Therefore, reconsideration and withdrawal of the rejections of claims 1, 11, 16 and 27, and all claims dependent therefrom, under 35 U.S.C. § 103(a) are respectfully requested.

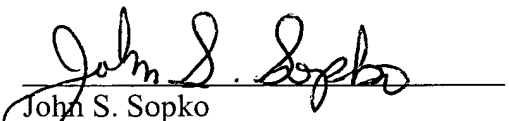
Summary

Therefore, Applicants respectfully submit that independent claims 1, 3, 8, 11, 16, 27, 29 and 32, and all claims dependent therefrom, are patentably distinct. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461.

Respectfully submitted,



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